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103D CONGRESS
1ST SESSION

H. R. 695

To amend the Public Health Service Act to establish an Office of Research on Women's Health, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 27, 1993

Ms. SNOWE introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Public Health Service Act to establish an Office of Research on Women's Health, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Women's Health Research Act of 1993''.

SEC. 2. ESTABLISHMENT OF OFFICE OF RESEARCH ON WOMEN'S HEALTH.

(a) IN GENERAL.—Title IV of the Public Health Service Act, as amended by section 2 of Public Law 101–613, is amended—

(1) by redesignating section 486 as section 485A;

(2) by redesignating parts F through H as parts G through I, respectively; and

(3) by inserting after part E the following new part:

''PART F—RESEARCH ON WOMEN'S HEALTH

"SEC. 486. OFFICE OF RESEARCH ON WOMEN'S HEALTH.

''(a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office to be known as the Office of Research on Women's Health (in this part referred to as the 'Office'). The Office shall be headed by a director, who shall be appointed by the Director of NIH.

''(b) PURPOSE.—The Director of the Office shall—

''(1) identify projects of research on women's health that should be conducted or supported by the national research institutes;

''(2) identify multidisciplinary research relating to research on women's health that should be so conducted or supported;

''(3) carry out paragraphs (1) and (2) with respect to the aging process in women, with priority given to menopause;

''(4) promote coordination and collaboration among entities conducting research identified under any of paragraphs (1) through (3);

''(5) encourage the conduct of such research by entities receiving funds from the national research institutes;

''(6) recommend an agenda for conducting and supporting such research;

''(7) promote the sufficient allocation of the resources of the national research institutes for conducting and supporting such research;

''(8) ensure that women are appropriately represented as subjects in projects of clinical research conducted or supported by the national research institutes; and

''(9) prepare the report required in section 486B.

''(c) COORDINATING COMMITTEE.—

''(1) In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Research on Women's Health (hereafter in this subsection referred to as the 'Coordinating Committee').

''(2) The Coordinating Committee shall be composed of the Directors of the national research institutes (or the designees of the Directors).

''(3) The Director of the Office shall serve as the chair of the Coordinating Committee.

''(4) With respect to research on women's health, the Coordinating Committee shall assist the Director of the Office in—

''(A) identifying the need for such research, and making an estimate each fiscal year of the funds needed to adequately support the research;

''(B) identifying needs regarding the coordination of research activities, including intramural and extramural multidisciplinary activities;

''(C) supporting the development of methodologies to determine the circumstances in which obtaining data specific to women (including data relating to the age of women and the membership of women in ethnic or racial groups) is an appropriate function of clinical trials of treatments and therapies;

''(D) supporting the development and expansion of clinical trials of treatments and

therapies for which obtaining such data has been determined to be an appropriate function; and

''(E) encouraging the national research institutes to conduct and support such research, including such clinical trials.

''(d) ADVISORY COMMITTEE.—

''(1) In carrying out subsection (b), the Director of the Office shall establish an advisory committee to be known as the Advisory Committee on Research on Women's Health (hereafter in this subsection referred to as the 'Advisory Committee').

''(2) The Advisory Committee shall be composed of no fewer than 12, and not more than 18 individuals, who are not officers or employees of the Federal Government. The Director of the Office shall make appointments to the Advisory Committee from among physicians, practitioners, scientists, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on research on women's health. A majority of the members of the Advisory Committee shall be women.

''(3) The Director of the Office shall serve as the chair of the Advisory Committee.

''(4) The Advisory Committee shall—

''(A) advise the Director of the Office on appropriate research activities to be undertaken by the national research institutes with respect to—

''(i) research on women's health;

''(ii) research on gender differences in clinical drug trials, including responses to pharmacological drugs;

''(iii) research on gender differences in disease etiology, course, and treatment;

''(iv) research on obstetrical and gynecological health conditions, diseases, and treatments; and

''(v) research on women's health conditions which require a multidisciplinary approach;

''(B) report to the Director of the Office on such research;

''(C) provide recommendations to such Director regarding activities of the Office (including recommendations on the development of the methodologies described in subsection (c)(4)(C) and recommendations on priorities in carrying

out research described in subparagraph (A)); and

''(D) assist in monitoring compliance with section 486(b)(8) regarding the inclusion of women in clinical research.

''(5)(A) The Advisory Committee shall prepare a biennial report describing the activities of the Committee, including findings made by the Committee regarding—

''(i) compliance with section 486(b)(8);

''(ii) the extent of expenditures made for research on women's health by the agencies of the National Institutes of Health; and

''(iii) the level of funding needed for such research.

''(B) The report required in subparagraph (A) shall be submitted to the Director of NIH for inclusion in the report required in section 403.

''(e) REPRESENTATION OF WOMEN AMONG RESEARCHERS.—The Secretary, acting through the Assistant Secretary for Personnel and in collaboration with the Director of the Office, shall determine the extent to which women are represented among senior physicians and scientists of the national research institutes and among physicians and scientists conducting research with funds pro-

vided by such institutes, and as appropriate, carry out activities to increase the extent of such representation.

''(f) DEFINITIONS.—For purposes of this part:

''(1) The term 'women's health conditions', with respect to women of all age, ethnic, and racial groups, means all diseases, disorders, and conditions (including with respect to mental health)—

''(A) unique to, more serious, or more prevalent in women;

''(B) for which the factors of medical risk or types of medical intervention are different for women, or for which it is unknown whether such factors or types are different for women; or

''(C) with respect to which there has been insufficient clinical research involving women as subjects or insufficient clinical data on women.

''(2) The term 'research on women's health' means research on women's health conditions, including research on preventing such conditions.

"SEC. 486A. NATIONAL DATA SYSTEM AND CLEARINGHOUSE ON RESEARCH ON WOMEN'S HEALTH.

''(a) DATA SYSTEM.—

''(1) The Director of NIH, in consultation with the Director of the Office, shall establish a data sys-

tem for the collection, storage, analysis, retrieval, and dissemination of information regarding research on women's health that is conducted or supported by the national research institutes. Information from the data system shall be available through information systems available to health care professionals and providers, researchers, and members of the public.

''(2) The data system established under paragraph (1) shall include a registry of clinical trials of experimental treatments that have been developed for research on women's health. Such registry shall include information on subject eligibility criteria, sex, age, ethnicity or race, and the location of the trial site or sites. Principal investigators of such clinical trials shall provide this information to the registry within 30 days after it is available. Once a trial has been completed, the principal investigator shall provide the registry with information pertaining to the results, including potential toxicities or adverse effects associated with the experimental treatment or treatments evaluated.

''(b) CLEARINGHOUSE.—The Director of NIH, in consultation with the Director of the Office and with the National Library of Medicine, shall establish, maintain,

and operate a program to provide information on research and prevention activities of the national research institutes that relate to research on women's health.

"SEC. 486B. BIENNIAL REPORT.

''(a) IN GENERAL.—With respect to research on women's health, the Director of the Office shall, not later than February 1, 1994, and biennially thereafter, prepare a report—

''(1) describing and evaluating the progress made during the preceding 2 fiscal years in research and treatment conducted or supported by the National Institutes of Health;

''(2) describing and analyzing the professional status of women physicians and scientists of such Institutes, including the identification of problems and barriers regarding advancements;

''(3) summarizing and analyzing expenditures made by the agencies of such Institutes (and by such Office) during the preceding 2 fiscal years; and

''(4) making such recommendations for legislative and administrative initiatives as the Director of the Office determines to be appropriate.

''(b) INCLUSION IN BIENNIAL REPORT OF DIRECTOR OF NIH.—The Director of the Office shall submit each report prepared under subsection (a) to the Director of

NIH for inclusion in the report submitted to the President and the Congress under section 403.

"SEC. 486C. AUTHORIZATION OF APPROPRIATIONS.

''For the purpose of carrying out this part, there are authorized to be appropriated $25,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''.

(b) REQUIREMENT OF SUFFICIENT ALLOCATION OF RESOURCES OF INSTITUTES.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (10), by striking ''and'' after the semicolon at the end;

(2) in paragraph (11), by striking the period at the end and inserting ''; and''; and

(3) by inserting after paragraph (11) the following new paragraph:

''(12) after consultation with the Director of the Office of Research on Women's Health, shall ensure that resources of the National Institutes of Health are sufficiently allocated for projects of research on women's health that are identified under section 486(b).''.

SEC. 3. OBSTETRICS AND GYNECOLOGY PROGRAM OF NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT.

Subpart 7 of part C of title IV of the Public Health Service Act (42 U.S.C. 285g et seq.) is amended by adding at the end the following section:

''PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY

''SEC. 452A. The Director of the Institute shall establish and maintain within the Institute an intramural laboratory and clinical research program in obstetrics and gynecology.''.

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